

## UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

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ATTORNEY DOCKET NO. SERIAL NUMBER FILING DATE FIRST NAMED INVENTOR 08/067,148 05/26/93 MONTAGNIER 3495 EXAMINER STUCKER, J 18N1/0712 ART UNIT PAPER NUMBER FINNEGAN, HENDERSON, FARABOW, GARRETT AND DUNNER 1300 I STREET, N.W. WASHINGTON, DC 20005-3315 1813 DATE MAILED: 07/12/94 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS Responsive to communication filed on 4/28 This application has been examined ろmonth(s); days from the date of this letter. A shortened statutory period for response to this action is set to expire Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133 Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION: 2. Notice of Draftsman's Patent Drawing Review, PTO-948. 1. Notice of References Cited by Examiner, PTO-892. 4. Notice of Informal Patent Application, PTO-152. 3. Notice of Art Cited by Applicant, PTO-1449. 5. Information on How to Effect Drawing Changes, PTO-1474. Part II SUMMARY OF ACTION 1. 1 Claims 15-36 are pending in the application. are withdrawn from consideration. have been cancelled. are allowed. 5. Claims are subject to restriction or election requirement. -7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes. 8. Formal drawings are required in response to this Office action. Under 37 C.F.R. 1.84 these drawings 9. The corrected or substitute drawings have been received on \_\_ are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948). \_\_\_\_ has (have) been approved by the 10. The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ examiner; disapproved by the examiner (see explanation). 11. The proposed drawing correction, filed \_\_\_\_\_\_\_ has been \_\_\_\_\_ approved; \_\_\_\_\_\_ disapproved (see explanation). 12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. \_\_\_\_\_\_; filed on \_\_\_\_\_\_ 13. Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. 14. Other

This Office Action is in response to the amendment filed 4/26/94. Claims 15-36 are pending and under final rejection.

Applicant's claim of priority to Great Britain application no. 83/24800 and South African application No. 84 7005 is acknowledged. The conditions of 35 USC 119 appear to have been met by the submission of certified copies of the priority documents in the grandparent case.

The submission of a new abstract is acknowledged.

The objection to the application because of alterations which have not been initialed and/or dated as is required by 37 C.F.R. §§ 1.52(c) and 1.56 is withdrawn.

The terminal disclaimer filed on 5/12/94 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of June 8, 2010 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The rejection of claims 15-21 and 32-36 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 7, and 9-11 of U.S. Patent No. 5217861 is withdrawn in view of the terminal disclaimer.

The rejection of claims 31 and 35 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment to the claims.

The rejection of claims 29-31 under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-3 and 8 of prior U.S. Patent No. 5217861 is withdrawn in view of Applicant's arguments.

Claims 29-31 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

Applicant's arguments have been fully considered but are not deemed to be persuasive.

Applicant has argued that utility is shown for example at page 4, lines 1-5, page 10, lines 21-25, and page 26, lines 15-21. The Examiner has inspected the referenced portions of the specification and can not conclude that the complexes per se have utility. For example, at page 4, lines 1-5, the utility of proteins i.e., antigens is described. At page 10, lines 21-25, the characterization of the recognition of viral antigens by antibodies sera is addressed. This is not a description of the use of the complex, but only a reaction product which is used in determining to which virus is the cause of infection, i.e., HIV or HTLV-1.

There is no intended use of the complex per se. Page 26, lines 15-21 describe that p25 can be a reagent for forming antibodies, and that the antibodies may be useful in the study of antigenic determinants. This does not constitute a use for the complexes per se.

Galfre et al is alleged to support Applicant's contention that the complex is useful as an intermediate for purifying the antigen The reference cited by Applicant teaches using the or antibody. antigens in immunoassays for detecting the presence of antibodies in a sample. This is in support of the Examiner's position that the complexes are merely the result of an immunoreaction and have no utility of their own. Applicant also invokes In re Irani to argue that the claimed complexes have utility. The analogy of an immune complex as a chemical intermediate is incorrect. intermediate of Irani, the compounds actually undergo a chemical change. In the case of immune complexes, the antigen and antibody are in close association but are otherwise unchanged. Therefore, the precedence of *Irani* is not pertinent. The claimed complexes have no patentable utility.

The specification is objected to and claims 15-36 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

This rejection remains in force as Applicant has not traversed this ground of rejection.

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. § 102(a) as being anticipated by Barre-Sinoussi et al.

Applicant's arguments have been fully considered but are not deemed to be persuasive.

Applicant argues that the South African and Great Britain patent applications antedate the reference and therefore render it improper as prior art. This is not convincing as the priority documents are enabled only for p25. The South African and Great Britain patent applications do not provide teachings of the antigens taught in Barre-Sinoussi et al. Therefore, the priority documents do not remove the rejection from the instant invention.

Claims 15-21 and 32-36 are rejected under 35 U.S.C. § 103 as being unpatentable over Barre-Sinoussi et al.

This rejection remains in effect for the same reasons as set forth in the 35 U.S.C. § 102(a) rejection, supra.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to

a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE IN NO EVENT WILL THE STATUTORY PERIOD FOR ADVISORY ACTION. RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

No claims are allowed.

Papers related this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 180 Fax numbers are: (703) 308-4227 and 305-3014.

The Fax center number for assistance is: (703) 308-4744.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jeffrey (703) 308-4237. Stucker whose telephone number is

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE M. NUCKER SUPERVISORY PATENT EXAMINER GROUP 180